DETAILED ACTION

The office action of 4/14/09 is vacated.

The examiner acknowledges receipt of request for extension of time filed 11/25/08 and 1/29/09; request for continued examination filed under 37 CFR 1.114, amendment and remarks filed 1/29/09. Claims 2 and 8-13 are canceled. Claims 1, 4, 5 and 14 are amended. New claims 16-18 are added. Claims 1, 3-5, 7 and 14-18 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/09 has been entered.

Response to Arguments

2. Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3-5, 7 and 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejections.

6. Claim 1 requires a sustained release pharmaceutical to consists (i) and (ii). The consisting language excludes the presence of granulating fluid that is required in all the compositions. Thus, a composition that does not have at least a granulating fluid is not envisioned at the time the invention is filed.

7. Correction and/or explanation are respectfully requested.

8. Claims 3, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 3 and 14 appear to violate the requirement of claim 1 that the sustained release matrix consists of (i) and (ii) because the comprising language of claim 14 opens up the matrix and the layered tablet of claim 3 appears to have matrix that comprises components other than (i) and (ii).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 3-5, 7 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Faour et al. (US 6,004,582).

Faour discloses a multi-layered delivery device (abstract), that is "useable in different environments for use of the osmotic device include biological environments such as the oral, ocular, nasal, vaginal, glands, gastrointestinal tract, rectum, cervical, intrauterine, arterial, venous, otic, sublingual, dermal, epidermal, subdermal, implant, buccal, bioadhesive, mucosal and other similar environments. Faour contemplates use of the device in different environments by stating, "likewise, it may be used in aquariums, industrial warehouses, laboratory facilities, hospitals, chemical reactions and other facilities" (column 4, lines 34-42). The dosage form is in the form of a tablet, pill, sphere, bar, plate or granule (column 6, line 7). The core of the tablet can comprise a number of agents such as osmagents, buffering agents, antioxidants, acacia, alginic acid, polyvinylpyrrolidone, methylcellulose, polyethylene glycol and many more that can be used with active agents in tablet formulation (column 9, line 28, 38-65; column 10, lines 14-57) and these materials such as acacia, the alginic acid, the polyvinylpyrrolidone used in the core or matrix of tablets meet the polymer requirements of claim 1 and new claim 17. The multi-layered nature of the dosage form meets claim 3. The limitation of new claim 16 is directed to the property of the composition and in the same way, the recitation that the pharmaceutically or nutritionally active agent "is not absorbed through the oral mucosa to a substantial extent" is a property of the composition with a note that substantial is relative. The process of preparation of the dosage form is exemplified in at least Examples 1-4 and method claim 14 reads on Faour's

method. Faour formulates a number of active agents as multilayered tablets (column 13, line 38 to column 16, line 44) and included in this list is riboflavin (column 16, line 31) with the teaching of the riboflavin meeting claim 7. The polyvinylpyrrolidone, methylcellulose and polyethylene glycol meet the limitation of new claim 17. The retaining means is a mucoadhesive and at least the hydroxypropylmethyl cellulose of Faour (column 6, line 26) meets the mucoadhesive of claims 4 and 15 and thus the retaining means of claims 1, 5 since claim 5 defines the retaining means as a holding device. At least the ethyl cellulose (column 6, line 27) meets new claim 18. The sustained release matrix composition of claim 1 reads on the layered dosage of Faour since each layer contains a matrix.

Response to Arguments

12. Applicant's arguments filed 1/29/09 have been fully considered but they are not persuasive.

13. Applicant argues that the Faour teaches semipermeable membrane that is not in the claimed invention. While the examiner agrees with the applicant that the claimed matrix composition does not have a semipermeable membrane, it is noted that the matrix composition is recited to comprise of … and the comprising language is open and does not exclude the presence of a membrane as disclosed in Faour.

14. Claims 1, 4, 5, 7 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Schiraldi et al. (US 4,713,243).

15. Schiraldi discloses bioadhesive extruded single or multilayered thin film for intra oral controlled releasing delivery (abstract; column 2, lines 22-27) for a number of therapeutically active agents such as doxycycline hyclate (column 3, line 51) with the doxycycline hyclate

anticipating the generic doxycycline of claim 7 and the generic pharmaceutically active agent of claim 1. The film composition adheres to the mucous membrane; the film, which is single or multilayered layered comprises water soluble or water swellable polymer matrix bioadhesive layer (column 2, lines 30-35), optionally contains reservoir and/or outer protective barrier membrane (column 2, lines 52-55), therapeutic agent contained in all the layers (column 2, lines 55-63). Polyethylene oxide and hydroxypropyl cellulose are film forming polymers of Schiraldi (column 3, lines 14 and 15). The polyethylene oxide and hydroxypropyl cellulose are listed in new claim 17 as the hydrophilic polymers of claim 1. The hydroxypropyl cellulose or homopolymer of ethylene oxide makes up the bioadhesive layer that adheres to the mucous surface (column 2, lines 35-37) so that the requirement for a retaining means of claim 1, which is further defined in claim 4 as a mucoadhesive is met as well as the retaining means of claim 5 because the holding device is the retaining means and mucoadhesive according to claims 4 and 5. The bioadhesive layer also contains water insoluble polymers such as ethyl cellulose, propyl cellulose, polyethylene and polypropylene (column 2, lines 48-41; column 3, lines 21-25) meeting the inert plastic of claim 1 that is further defined in new claim 18 such that the ethyl cellulose and polyethylene of Schiraldi meet claim 1 and new claim 18. Claim 7 defines what the active agents of claim 1 could be and because one of Schiraldi's active agent is doxycycline and meets claim 7, the property of the active agent recited in claim 16 is also applicable to the doxycycline so that new claim 16 is met. Thus Schiraldi anticipates claims 1, 4, 5, 7 and new claims 16-18.

16. Claims 1, 4, 5, 7 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lerner et al. (US 6,197,331).

Lerner discloses controlled release solid composition for the oral cavity or pharmaceutical oral patch (abstract) with the disc of claims 14 and 15 reading on the patch; the composition contains adhesive and release layer (column 8, lines 20-25) meeting the requirement for layered dosage form in which one surface is adhesive, thus meeting claim 4 and another surface, non-adhesive (column 7, lines 53 and 54); polymer in the adhesive layer is EUDRAGIT type polymer (column 11, lines 24 and 25; column 7, lines 25-28, 45-50); the matrix can also contain plasticizers such as polyethylene glycol, castor oil (column 11, line 66 to column 12, line 5) with the polymer or the oil meeting new claim 17. Lerner specifically teaches that "any agent can be used, depending on the purpose of therapy" (column 15, lines 12 and 13) and proceeds to name specific ones and cyclosporin is mentioned as a peptide or protein drug (column 16, lines 52-56) meeting claim 7. The mixing of the polymer with the active agent and eventually formulating the composition into patch (column 17, lines 26-34) meets the requirements of the method claims 14 and 15. The limitation of new claim 16 is directed to the property of the composition and in the same way, the recitation that the composition "is not absorbed through the oral mucosa to a substantial extent is a property of the composition so that Lerner meets the claim. Lerner thus teaches all the limitations of the designated claims. The adhesive material which includes EUDRAGIT (column 11, lines 16-53) meets claim 4 and thus the retaining device of claims 1, 5 and 15 is met. Other polymers such as polyacrylate, polymethacrylate, cellulose derivatives, ethylcellulose, hydroxypropylmethyl cellulose, cellulose acetate phthalate, polysaccharide, guar gum, pectin, alginic acid and salts thereof, xanthan gum, gum tragacanth,

gum arabic, starch, chitin, chitosan, proteins, polyamino acids, polypeptides, gelatin, polyglycolic acid, polylactic acid, polyglycolic-polylactic copolymers, cross-linked polysaccharides, and cross-linked protein (column 11, lines 16-23) and when ethyl cellulose is used, claims 1 reciting inert plastic as the polymeric material and new claim 18 defining what the inert plastic is are met.

Response to Arguments

17. Applicant's arguments filed 1/29/09 have been fully considered but they are not persuasive.

18. Applicant says that Lerner teaches the presence of plasticizer that is not included in the claimed composition. While the examiner agrees with the applicant that the claimed invention does not say that the matrix composition consists of plasticizer, the examiner notes that the matrix composition of claim 1 "comprises --- location" and the comprising language is open and does not exclude the plasticizer of Lerner.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618